**DEXTROSE - dextrose monohydrate injection, solution**
Baxter Healthcare Corporation

## DESCRIPTION

Dextrose Injections, USP are sterile, nonpyrogenic, hypertonic solutions for fluid replenishment and caloric supply in single dose containers for intravenous administration after compounding. They contain no antimicrobial agents. Composition, osmolarity, pH, and caloric content are shown in Table 1.

**Table 1**

| | **Composition** | **Osmolarity** (mOsmol/L) (calc.) | **pH** | **Caloric Content&**(kcal/L) | **How Supplied** | |
|---|---|---|---|---|---|---|
| | Dextrose Hydrous, USP(g/L) | | | | **Size** | |
| | | | | | 500 mL in 1000 mL unit | 1000 mL in 2000 mL unit |
| | | | | | Code and NDC | |
| 10% Dextrose Injection, USP | 100 | 505 | 4.0 (3.2 to 6.5) | 340 | 2B0174 NDC 0338-0023-13 | 2B0176 NDC 0338-0023-34 |
| 20% Dextrose Injection, USP | 200 | 1010 | 4.0 (3.2 to 6.5) | 684 | 2B0124 NDC 0338-0711-13 | 2B0126 NDC 0338-0711-34 |
| 30% Dextrose Injection, USP | 300 | 1510 | 4.0 (3.2 to 6.5) | 1030 | 2B0134 NDC 0338-0713-13 | 2B0136 NDC 0338-0713-34 |
| 40% Dextrose Injection, USP | 400 | 2020 | 4.0 (3.2 to 6.5) | 1370 | 2B0154 NDC 0338-0715-13 | 2B0156 NDC 0338-0715-34 |
| 50% Dextrose Injection, USP | 500 | 2520 | 4.0 (3.2 to 6.5) | 1710 | 2B0264 NDC 0338-0031-13 | 2B0266 NDC 0338-0031-34 |
| 60% Dextrose Injection, USP | 600 | 3030 | 4.0 (3.2 to 6.5) | 2050 | 2B0104 NDC 0338-0717-13 | |
| 70% Dextrose Injection, USP | 700 | 3530 | 4.0 (3.2 to 6.5) | 2390 | 2B0114 NDC 0338-0719-13 | |

The Viaflex® plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146® Plastic). Exposure to temperatures above 25ºC/77ºF during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

## CLINICAL PHARMACOLOGY

Dextrose Injections, USP have value as a source of water and calories. They are capable of inducing diuresis depending on the clinical condition of the patient.

## INDICATIONS AND USAGE

Dextrose Injections, USP are indicated as a caloric component in a parenteral nutrition regimen. They are used with an appropriate protein (nitrogen) source in the prevention of nitrogen loss or in the treatment of negative nitrogen balance in patients where: (1) the alimentary tract cannot or should not be used, (2) gastrointestinal absorption of protein is impaired, or (3) metabolic requirements for protein are substantially increased, as with extensive burns.

**CONTRAINDICATIONS**
The infusion of hypertonic dextrose injections is contraindicated in patients having intracranial or intraspinal hemorrhage, in patients who are severely dehydrated, in patients who are anuric, and in patients in hepatic coma.
Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

**WARNINGS**
Dilute before use to a concentration which will, when administered with an amino acid (nitrogen) source, result in an appropriate calorie to gram of nitrogen ratio and which has an osmolarity consistent with the route of administration.
Unless appropriately diluted, the infusion of hypertonic dextrose injection into a peripheral vein may result in vein irritation, vein damage, and thrombosis. Strongly hypertonic nutrient solutions should only be administered through an indwelling intravenous catheter with the tip located in a large central vein such as the superior vena cava.
In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.
WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.
Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

**PRECAUTIONS**
Administration of hypertonic dextrose and amino acid solutions via central venous catheter may be associated with complications which can be prevented or minimized by careful attention to all aspects of the procedure. This includes attention to solution preparation, administration and patient monitoring.
**It is essential that a carefully prepared protocol, based upon current medical practice, be followed, preferably by an experienced team**. The package insert of the protein (nitrogen) source should be consulted for dosage and all precautionary information.
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
Care should be taken to avoid circulatory overload, particularly in patients with cardiac insufficiency.
Caution must be exercised in the administration of these injections to patients receiving corticosteroids or corticotropin.
These injections should be used with caution in patients with overt or subclinical diabetes mellitus.
Drug product contains no more than 25 µg/L of aluminum.

**Carcinogenesis and Mutagenesis and Impairment of Fertility.**
Studies with Dextrose Injection, USP, have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

**Pregnancy:**

Teratogenic Effects

Pregnancy Category C.
Animal reproduction studies have not been conducted with Dextrose Injections, USP. It is also not known whether Dextrose Injections, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose Injections, USP should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:**
Caution should be exercised when Dextrose Injection, USP, is administered to a nursing woman.

**Pediatric Use:**
Dextrose is safe and effective for the stated indications in pediatric patients (see **Indications and Usage**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/ hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

**ADVERSE REACTIONS**
Too rapid infusion of a hypertonic dextrose solution may result in diuresis, hyperglycemia, glycosuria, and hyperosmolar coma. Continual clinical monitoring of the patient is necessary in order to identify and initiate measures for these clinical conditions.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

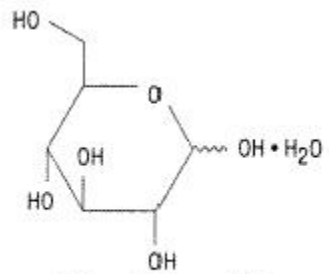
**DOSAGE AND ADMINISTRATION**
Following suitable admixture of prescribed drugs, the dosage is usually dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations. See directions accompanying drugs.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
Do not administer unless solution is clear and seal is intact.
These admixed injections in Viaflex® plastic containers are intended for intravenous administration using sterile equipment.
Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

**HOW SUPPLIED**
See Table 1.
Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended the product be stored at room temperature (25ºC/77ºF).

**DIRECTIONS FOR USE OF VIAFLEX® PLASTIC CONTAINER**

**WARNING:**
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

**Preparation for Administration**
1. Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.
2. Insert transfer set into prepared solution container to be transferred. Follow directions accompanying transfer set.
3. Remove protector from extended middle port of dextrose solution container and insert connector of transfer set.
4. Transfer solution by gravity or by using a Viavac® unit.
5. After desired solution has been transferred, mix thoroughly and seal extension tubing of extended middle port. Cut between seal and connector of transfer set.
6. Check for leaks.
7. **Warning**: Additives may be incompatible. Supplemental medication may be added with a 19 to 22 gauge needle through the medication injection site on the dextrose solution container. Mix solution and medication thoroughly. For high density medications, such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.
8. Suspend container from eyelet support.
9. Remove plastic protector from outlet port at bottom of container.
10. Attach administration set. Refer to complete directions accompanying set.
The structural formula of Dextrose Hydrous, USP is:



Dextrose Hydrous, USP
(α-Glucose monohydrate)

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Printed in USA